3. NON-TECHNICAL ABSTRACT

Approximately 220,000 new cases of prostate cancer are diagnosed each year in the United States and estimates are that 28,900 men died from this disease in 2003. Most men with localized disease receive initial therapies consisting of surgical removal of the prostate gland and radiation treatments. Despite these treatments, the cancer will recur in 30 to 50% of the patients. The recurrence of prostate cancer is most often first diagnosed as an increase in the level of prostate-specific antigen (PSA).

The purpose of this study is to see if we can safely immunize against cancer proteins found in prostate cancer using a biologic product called the P501 Immunotherapeutic Vaccine. In particular, we are trying to generate an immune response against the P501 protein, which is only expressed in prostate cells. The P501 Immunotherapeutic Vaccine contains two components: 1) 1) a recombinant Adenovirus-5 containing the P501 gene (Ad/P501) and 2) a recombinant P501 protein plus an adjuvant (CPC-P501/AS15). The Ad/P501 is a laboratory-modified form of adenovirus that has been engineered to contain the gene for the P501 protein. This virus is replication-deficient, which means it cannot grow in the human body. The CPC-P501/AS15 is a recombinant protein produced in yeast cells and combined with an adjuvant. An adjuvant is a component of a vaccine that helps to increase the immune response to the vaccine antigen.

The Ad/P501 is designed to initiate and stimulate an immune response to the P501 protein consisting of particular cells of the immune system called cytotoxic T lymphocytes. The CPC-P501/AS15 is designed to stimulate another type of T lymphocytes called helper T cells as well as an antibody response to the P501 protein. The Ad/P501 and CPC-P501/AS15 are separate components of the vaccine regimen that are designed to have different functions in the proposed therapeutic application.

Cancer patients will initially receive two intramuscular (IM) injections of Ad/P501 at the beginning of the study and two weeks later. Starting two weeks after completion of the Ad/P501 injections, patients will also receive IM injections of CPC-P501/AS15 every three weeks for a total of three CPC-P501/AS15 immunizations. Groups of patients will receive increasing doses of Ad/P501. Because of this, the first patients to be treated in this study will receive lower doses of Ad/P501 than the later patients, watching for side effects to be sure that it is safe to give the higher doses. We believe, based on laboratory experiments, that the use of this vaccine could result in the production of immune system cells and antibodies that recognize prostate cancer cells. Production of immune system cells and antibodies that recognize prostate cancer cells might provide therapeutic benefit.